REMARKS

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

Currently, claims 113-129 are pending in the present application, including independent claim 113. Independent claim 113, for instance, is directed to a diagnostic device having a housing that defines i) an opening for receiving a sample, ii) a first chamber into which the sample may be directed, iii) a first channel positioned to provide unreacted sample from the opening to the first chamber, and iv) a second channel positioned to remove unreacted sample from the first chamber. A test strip is removably attached to the housing that defines a test surface in fluid communication with the first chamber so that the sample may be reacted. A second chamber is positioned for receipt of unreacted sample from the first chamber. The second chamber is in fluid communication with the second channel. The device also includes means for inducing a negative pressure differential on the sample to direct the sample through the first channel, into the chamber, to the test surface, and to thereafter remove an unreacted portion of the sample from the test surface, through the second channel, and into the second chamber.

The Office Action also rejected independent claim 113 under *35 U.S.C. § 103(a)* as being obvious over U.S. Patent No. 5,677,133 to Oberhardt. Oberhardt is directed to a method for performing an affinity assay comprising: (1) contacting a sample to be assayed for the presence of an analyte with a dry reagent containing the analyte bound to a reaction cascade initiator, an antibody reactive with the analyte, and magnetic particles, to form an assay mixture in a reaction chamber; (2) incubating the assay

mixture; (3) applying an oscillating or moving static magnetic field to the assay mixture; (4) activating the reaction cascade initiator to initiate a reaction cascade; (5) monitoring the response of the magnetic particles to the oscillating or rotating magnetic field to provide a time varying signal; and (6) determining the analyte concentration of the sample by analysis of the time varying signal. (Col. 4, lines 48-64). Oberhardt describes carrying out its affinity assay method using a reaction slide, such as shown in Figures 1-4.

However, Oberhardt lacks certain limitations of independent claim 113. Oberhardt indicates the use of a vacuum to cause movement of a sample from a sample well to a reaction chamber. To use such vacuum, Oberhardt uses a liquid impermeable membrane to pull the liquid sample to the reaction chamber without removing the liquid sample from the reaction chamber. More specifically, no additional channel or additional chamber is provided for receipt of the liquid sample from the reaction chamber because the liquid sample is not removed from Oberhardt's reaction chamber. In fact, such liquid could not be removed from Oberhardt's reaction chamber with a vacuum because Oberhardt specifically indicates the placement of a liquid impermeable membrane on vent 76 of the reaction chamber in order to draw a vacuum without removing the liquid sample.

Thus, unlike the limitations of independent claim 113, Oberhardt does not indicate "a second channel positioned to remove unreacted sample from the first chamber" because Oberhardt does not remove liquid sample from the reaction chamber. In addition, unlike the limitations of independent claim 113, Oberhardt does

not indicate "a second chamber positioned for receipt of unreacted sample from the first chamber" because Oberhardt does not remove liquid sample from its reaction chamber.

The Office Action responds to this argument by stating that figures 11A(1)-11C depict a plurality of channels, and further, that mere duplication of parts has no patentable significance. Figures 11A(1)-11C illustrate a means for conducting a panel test (i.e., different reaction components, different durations of drying, different temperature in dry chemistry preparation, etc.). Additionally, the Office Action indicates "it would have been obvious to a person of ordinary skill in the art to incorporate additional channels and openings to Oberhardt's invention because it would be desirable and more efficient to have a plurality of channels and openings to allow more than one sample to be analyzed simultaneously, or alternatively, it would allow one sample to undergo multiple analyses simultaneously." Applicants are unsure of how this response applies to their argument. Nothing in the pending claims indicate "duplicating parts" in order to be more efficient by analyzing more than one sample. The pending claims indicate a structure that performs a wholly different task than Oberhardt. One embodiment that the pending claims encompass is illustrated in Applicant's Figs. 5-7, provided below for Examiner's convenience:

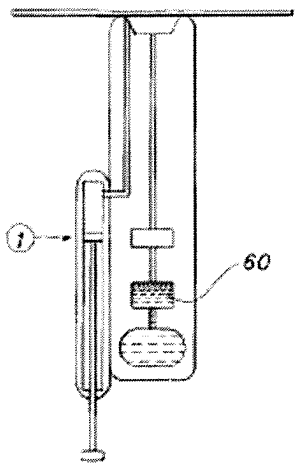

FIG 5

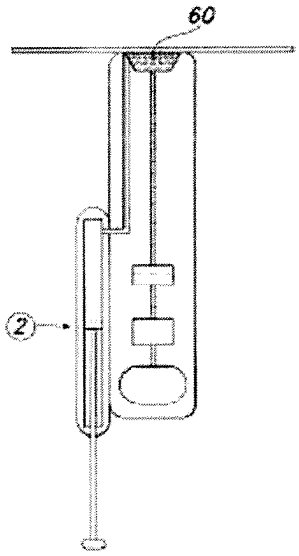

FIG 6

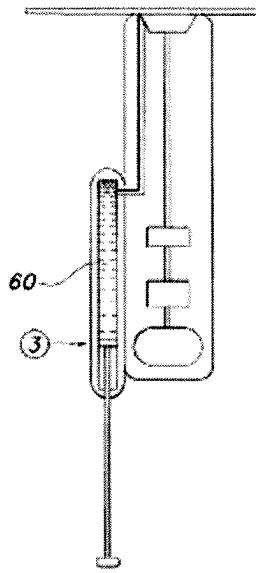

FIG 7

As illustrated, an opening receives the unreacted sample, as negative pressure is applied on the system by the syringe, the unreacted sample travels through a first channel into a first reaction chamber that contacts a test strip (Fig. 6). As further negative pressure is applied, the remaining excess sample travels through a second channel into a second chamber. Thus, the sample is removed from the test strip utilizing negative pressure.

Nothing in independent claim 113 indicates merely "duplicating parts." Oberhardt is **not** configured to remove unreacted sample from the reaction chamber utilizing negative pressure. In fact, Oberhardt actually employs a structure to ensure that no sample leaves the reaction chamber:

> In order to use the vacuum or pressure methods, it is preferred that a hydrophobic membrane (51) be installed over vent (76) of reaction chamber (62) as shown in FIGS. 4a and 4b. The hydrophobic membrane must be gas permeable but liquid impermeable. . . . In addition, the

> conduit leading from the sample well to the reaction chamber must be nonwetting or minimally wetting, such that it does not automatically provide capillary action to transport the liquid. This appropriate degree of wetting may be achieved by selection of plastic materials or use of coatings with resultant high contact angles at the liquid/solid interface. Col. 6, line 62 – Col. 7, line 11.

As such, Oberhardt actually teaches away from the removing the liquid sample from the reaction chamber.

Furthermore, unlike the limitations of independent claim 113, Oberhardt does not have "means for inducing a negative pressure differential on the sample to direct the sample through the first channel, into the chamber, to the test surface, and to thereafter remove an unreacted portion of the sample from the test surface and into the second chamber" because Oberhardt does not remove any sample from its reaction chamber and does not have a second chamber.

The Office Action responds to this argument stating that Oberhardt discloses a syringe. Indeed, Oberhardt does disclose a syringe, but the syringe is only configured to provide positive pressure. In the above quotation from Oberhardt (Col. 6, line 62 – Col. 7, line 11) it is indicated that conduit from the sample well to the reaction chamber must be configured so that the sample is not transported back to the sample well from the reaction chamber. So, again, Oberhardt actually teaches away from this claimed limitation.

Moreover, independent claim 113 also requires a test strip that *defines a test surface* and that is *removably attached* to a housing and is in fluid communication with the first chamber by a second opening formed in the first chamber. In this manner, the test strip may be easily removed for viewing or placement in an analyzer. In contrast,

Oberhardt's reaction plate 20 itself defines or forms part of the reaction chamber 62 (Fig. 4A). Unlike claim 113, reaction plate 20 is not removably attached to a housing. Finally, Oberhardt's reaction plate 20 is not attached a housing that comprises a second opening for reacting the sample.

The Office Action responds to this argument stating that "a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art." Applicant does not understand this response. If Oberhardt is configured with a reaction plate that is not removably attached, then an element that is removably attached would inherently result in a structural difference.

In any event, a prima facie case of obviousness is made only when the claimed invention *taken as a whole* is obvious based a modification of a reference. In this case, even if one were motivated to employ multiple "channels" and "chambers" as suggested in the Office Action, no reasonable justification exists for doing so in the specific manner claimed. Plainly, the only incentive or motivation for so modifying Oberhardt in the manner suggested in the Office Action results from using Applicants' disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings in the prior art, which is improper under *35 U.S.C. § 103*.

Thus, for at least the reasons set forth above, Applicants respectfully submit that the present claims are not anticipated by Oberhardt. Furthermore, Applicant respectfully submits that some or all of the dependent claims also contain additional limitations not indicated by Oberhardt. By way of example only, claim 117 requires that the means for inducing a negative pressure is a syringe, and claim 118 requires the

syringe to have indicators correlated with the rest of the device so as to mark the position of the sample within the device.

It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Ramillano is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Response.

Please charge any additional fees required by this Response to Deposit Account No. 04-1403.

Respectfully submitted,

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